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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/790,449	02/19/2004	Wei-Cheng Wang	P-3641.274	9920

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EXAMINER	
FLORY, CHRISTOPHER A	

ART UNIT	PAPER NUMBER
3762	

DATE MAILED: 11/27/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/790,449	WANG, WEI-CHENG	
	Examiner	Art Unit	
	Christopher A. Flory	3762	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *08 September 2006*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1 and 3-9* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1 and 3-9* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Claim Rejections - 35 USC § 102

1. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

2. Claims 1-9 stand rejected under 35 U.S.C. 102(e) as being anticipated by Unsworth et al. (US Patent 6,615,080, hereinafter Unsworth'080).

Regarding claims 1-6, Unsworth'080 discloses a method of generating a stimulation signal to non-invasively stimulating the stimulation points surrounding K1 and FHA acupuncture points (Figs. 7 and 10; ABSTRACT; column 3, lines 50-55) with at least a set of non-invasive electrical stimulation (Fig. 7, electrodes 6a and 6b); said method comprising mounting a non-invasive stimulation device onto the stimulation points (electrodes are disclosed as being self-adhesive in column 5, line 65 through column 6, line 3); wherein the stimulating comprises at least a set of non-invasive electrical stimulation pulses (column 5, line 44 through column 6, line 11).

Regarding the clause "of/for moderating lower and upper back pain in a patient," it has been held that a recitation of the *intended use of the claimed invention must result in a structural difference between the claimed invention and the prior art* in order to patentably distinguish the claimed invention from the prior art. If the prior art structure is

capable of performing the intended use, then it meets the claim. In this case, the structure of the Unsworth'080 device is capable of delivering electrical stimulation to the sole of the foot in the same manner as the claimed invention, and would therefore logically and expectably be capable of the intended use of relieving back pain. Unsworth et al. discloses the device as being effective in increasing blood flow in the stimulated region (column 6, lines 4-11), which Applicant discloses in paragraph [22] as a component of end result of back pain relief. Therefore, the claimed invention does not distinguish over the Stevenson et al. reference.

It is noted that, although Unsworth'080 does not explicitly state placement over the K1 and FHA acupuncture points, it is clear from Fig. 10 of Unsworth'080 and Fig. 1a of the instant application that the Unsworth et al. device delivers electrical stimulation to the claimed foot regions of the ball and heel (column 3, lines 50-55) *which would inherently result in stimulation of points surrounding the K1 and FHA acupuncture points*, and therefore the claimed invention does not distinguish over the prior art.

Regarding claim 7, Unsworth'080 shows a multiple electrode carrying insole (Fig. 7, insert 17) housed in a shoe-like device (Fig. 7, footwear 15) carrying the at least two electrodes (electrodes 6a and 6b) and a circuit for generating the stimulation signal (NMES device 10; column 5, line 43 through column 6, line 11); providing a securing means for mounting the at least two electrodes on the said insole (column 10, lines 9-26).

Regarding claim 8, Unsworth et al. discloses a delivering step comprising delivering an intermittent stimulation signal (column 5, lines 52-63). The intermittent stimulation signal is taken to be the cycle of 12 seconds on and 48 seconds off.

Regarding claim 9, Unsworth et al. discloses a delivering step comprising a continuous stimulation signal (column 5, lines 52-63). The continuous signal is considered to be the biphasic square wave pulses that are delivered for a continuous 12 seconds. Likewise, it is understood from the user interface as disclosed in Unsworth et al., that the device continues to deliver biphasic pulses in a 12 seconds on, 48 seconds off manner until the user adjusts the intensity dial to zero (i.e. "off"). Therefore, this can be considered a stimulation signal (wherein the signal is considered to be the overall stimulation pattern) that is delivered continuously from the time the device is put on until the user makes the decision to take the device off or turn the stimulus intensity to zero, or effectively turn the device off. Given either or both interpretations, this claim limitation of the instant application does not distinguish over the prior art.

Response to Arguments

3. Applicant's arguments, see paragraph 1 of page 1, filed 8 September 2006, with respect to objections to the Abstract and Specification, as well as rejections of claims 2 and 4 under 35 U.S.C. §112, second paragraph, have been fully considered and are persuasive. The objection to the Abstract and Specification, and the §112 rejection of claims 2 and 4 has been withdrawn.

4. Applicant's arguments, see page 1, paragraph 2 and page 3, paragraph 3, filed 8 September 2006, with respect to the rejection of claims 1-7 and 9 under 35 U.S.C. §102(b) as being anticipated by Stevenson'087 have been fully considered. Although the arguments posed are not themselves persuasive, the amendment of the claim 1 to specifically include the limitation of pulses of electrical stimulation is not met by the Stevenson'087 reference, which only delivers constant, DC battery stimulation. The rejection of claims 1-7 and 9 over Stevenson'087 has been withdrawn.

5. Applicant's arguments, see paragraph 1 of page 2, filed 8 September 2006, with respect to the Official Notice rejection of claim 1 have been fully considered and are persuasive. The rejection of claim 1 has been withdrawn.

6. Applicant's arguments filed 8 September 2006 regarding the rejection of claims 1-9 under 35 U.S.C. §102(e) as being anticipated by Unsworth'080 have been fully considered but they are not persuasive.

In response to applicant's argument that Unsworth'080 teaches NMES stimulation of the insole only to treat a claimed disease whereas the instant Application teaches NMES stimulation through specific acupuncture points on the insole to treat back pain, the fact that applicant has recognized another advantage which would flow naturally from following the suggestion of the prior art cannot be the basis for patentability when the differences.would otherwise be obvious. See *Ex parte Obiaya*, 227 USPQ 58, 60 (Bd. Pat. App. & Inter. 1985). Further explanation can be found in section 2 of paragraph 2 above.

Applicant further concedes that delivery of electrical stimulation to acupuncture points is not novel or distinguishable over prior art. This supports the Examiner's finding that the Unsworth'080 device would inherently stimulate stimulation points *surrounding* the K1 and FSA acupuncture points.

In response to applicant's argument that Unsworth'080 does not disclose moderating lower and upper back pain, a recitation of the intended use of the claimed invention must result in a structural difference between the claimed invention and the prior art in order to patentably distinguish the claimed invention from the prior art. If the prior art structure is capable of performing the intended use, then it meets the claim.

Conclusion

7. **THIS ACTION IS MADE FINAL.** Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Christopher A. Flory whose telephone number is (571) 272-6820. The examiner can normally be reached on M - F 8:30 a.m. to 5:00 p.m..

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Angela Sykes can be reached on (571) 272-4955. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Christopher A. Flory

20 November 2006

George Manuel
Primary Examiner